

**Remarks**

This Amendment is responsive to the Office Action dated September 11, 2008. Claims 1-12, 14-16, 18-20, 24, 25, and 31-46 are pending in the present application. Claim 36 has been amended in view of a previous amendment to claim 1. Claims 47-49 are added herein. Support for new claims 47-49 can be found in the present specification, for example, at page 6, first full paragraph, and page 14, first full paragraph.

Entry of the foregoing amendments and reconsideration of the rejections set forth in the Office Action are respectfully requested.

**Present Invention**

Claims 1-12, 14-16, 18-20, 24, 25, and 31-46 are pending in the present application. The present invention is directed to a homogeneous, thermoreversible gel film comprising a film forming amount of kappa-2 carrageenan, and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent; wherein said film:

- (i) further comprises sodium cation,
- (ii) has a solids content of at least 50% based on all components in the gel film, and
- (iii) has a break force strength of at least 1,500 grams.

The present invention is also directed to soft capsules and solid forms comprising the foregoing gel film.

As detailed below, kappa-2 carrageenan was known to have a different chemical structure and different physical properties than kappa carrageenan, iota carrageenan and physical mixtures thereof. In particular, as noted in the present specification, as well as set forth in the art cited by the Applicants and the Examiner, kappa-2 carrageenan was considered to be weakly gelling. To Applicants' surprise, the gels of the present invention

comprising kappa-2 carrageenan have been found to form surprisingly strong gel films. None of the art cited by the Examiner suggests otherwise.

**Restriction Requirement**

A written restriction requirement and election of species dated October 15, 2007, was issued in the present application. At page 2 of the Office Action dated September 11, 2008, the Examiner noted that claims drawn to the elected invention had been inadvertently withdrawn in the previous Office Action. Applicants note with appreciation that the Examiner has accepted Applicants' request to reinstate the inadvertently withdrawn claims that are directed to the elected invention. As a result, as noted above, the pending claims are: 1-12, 14-16, 18-20, 24, 25, and 31-46.

**35 USC § 103**

At pages 4-8 of the Office Action, the Examiner rejected: (i) claims 1-11, 14-16, 18-20, 24-25, 34-39, 42 and 44-46 under 35 USC § 103 as being unpatentable over Gilleland in view of de Vries and van de Velde; and (ii) claims 1, 38-40, and 42-44 under 35 USC § 103 as being unpatentable over Gilleland in view of de Vries and van de Velde as applied to claims 1-11, 14-16, 18-20, 24-25, 34-39, 42 and 44-46 and further in view of Parikh.

The Examiner cites Gilleland for teaching that kappa and iota carrageenans provide good performance in gel film applications. The Examiner acknowledges that Gilleland does not teach the specific use of kappa-2 carrageenan in such applications. The Examiner indicates that de Vries teaches that kappa-2 carrageenan has properties that are intermediate to both kappa and iota carrageenan (citing Table 1 in de Vries) and further acknowledges that de Vries does not teach the presence of sodium cations (see the Office Action at page 11, first

full paragraph). The Examiner newly cites van de Velde as teaching kappa-2 carrageenan containing sodium cations and for teaching that iota and kappa carrageenans act independently of one another and gel at different temperatures. The Examiner argues that van de Velde suggests that kappa-2 carrageenan would have the added benefit of conferring properties intermediate to both kappa and iota carrageenans without the two physically separating and acting independently. Therefore, the Examiner concludes that one skilled in the art would have found it obvious to combine the starch based capsule teachings of Gilleland with the teachings of de Vries and van de Velde to arrive at the presently claimed invention.

Applicants respectfully traverse the foregoing rejections on the basis that the cited prior art, alone or in any combination, does not disclose or suggest: (i) the gel films of the present invention comprising kappa-2 carrageenans, sodium cation, solids content and break force strength; or (ii) soft capsules and solid forms comprising such gel films. As detailed by the Applicants in the present specification, and as further explained below, kappa-2 carrageenan was known to have a different chemical structure and different physical properties than kappa carrageenan, iota carrageenan or physical mixtures thereof, and was expected to weakly gelling. None of the prior art cited by the Examiner suggest that kappa-2 carrageenan of the present invention could be used in place of kappa carrageenan, iota carrageenan or physical mixtures thereof in the gel films, soft capsules and solid forms of the present invention having the claimed break force strength.

As explained in the Amendment filed on May 20, 2008, Gilleland does not disclose or suggest kappa-2 carrageenan or any particular cations to be used to gel kappa-2 carrageenan, and de Vries, Table 1, state that the metal “required for gelling” kappa-2 carrageenan is both calcium and potassium. There is no disclosure or suggestion in either of these references of a

kappa-2 gel film containing sodium that, in a solids system of at least 50 wt%, would have a break force strength of at least 1,500 grams or any disclosure or suggestion that soft capsules or solid forms could contain such kappa-2 carrageenan gel films. Neither of the newly cited references (van de Velde and Parikh) cited by the Examiner in the foregoing rejections cure the deficiencies of Gilleland and de Vries; in fact, Applicants submit that van de Velde supports the patentability of the present invention.

At pages 4-6 of the present specification, Applicants explained that all carrageenans contain repeating galactose units joined by alternating  $\alpha 1 \rightarrow 3$  and  $\beta 1 \rightarrow 4$  glycosidic linkages and are sulfated to widely varying degrees. The types of carrageenan may be distinguished, in part, by their degree and position of sulfation, as well as the seaweed from which they are obtained. For example, iota carrageenan has a repeating unit of D-galactose-4-sulfate-3,6-anhydro-D-galactose-2-sulfate providing a sulfate ester content of about 25 to 34%. Kappa carrageenan has a repeating unit of D-galactose-4-sulfate-3,6-anhydro-D-galactose and is obtained, for example, from *Kappaphycus alvarezii* (also known as "*Eucheuma cottonii*"). In contrast, kappa-2 carrageenan is reported by R. Falshaw, H.J. Bixler and K. Johndro, *Structure and Performance of Commercial Kappa-2 Carrageenan Extracts*, Food Hydrocolloids 15 (2001) 441-452, and by H. Bixler, K Johndro and R Falshaw, *Kappa-2 carrageenan: structure and performance of commercial extracts II*, Food Hydrocolloids 15 (2001) 619-630 to be copolymers containing a certain amount of kappa repeating units (3:6-anhydrogalactose (3:6-AG)) and iota repeating units (3:6-anhydrogalactose-2-sulfate (3:6-AG-2-S)) covalently bound in the copolymer backbone and obtained from certain *Gigartinaceae* algae. These references (previously cited in an IDS) state that such kappa-2 carrageenans have distinctly different properties as compared to simple mixtures of kappa and iota carrageenans. Other studies (such as van de Velde) have also indicated that kappa-2

carrageenans are copolymers containing kappa and iota repeating units covalently bound (in certain ratios of kappa to iota moieties) in the copolymer backbone in clear distinction to physical mixtures of kappa and iota polymers. As a result of these differences, as noted, for example, at page 10 of the present specification, kappa-2 carrageenan was known to be weakly gelling and it would have been expected that such weakly gelling carrageenans would form weak gel films.

No references have been cited by the Examiner to suggest that kappa-2 carrageenans are sufficiently similar in structure to kappa carrageenan, iota carrageenan or physical mixtures thereof so as to lead to the alternative conclusion; i.e., that kappa-2 carrageenan would be expected to have similar properties as kappa carrageenan, iota carrageenan or physical mixtures thereof.

Indeed, Applicants further refer to the following reference submitted in an IDS on November 20, 2008: Marine Colloids Application Bulletin, G-39, 1990 ("Technical Bulletin").<sup>1</sup> This Technical Bulletin discusses the water gelling properties of various carrageenans. In particular, this Technical Bulletin states the following:

"In order to consider a carrageenan for use in an aqueous gelling application, the prospective user should be familiar with the basic types of carrageenan that are available, their properties and how to use them in the system...The two basic water gelling carrageenans are kappa and iota...The kappa-2 carrageenan has properties intermediate between kappa and iota, however, it produces rather soft gels, therefore it is not often used by itself for preparation of water gels."

See pages 2 and 6 of the Technical Bulletin (emphasis added).

This Technical Bulletin does not list kappa-2 carrageenan as a known water gelling carrageenan and, further, states that because it is known to produce soft gels, "it is not often

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<sup>1</sup> A copy of this Technical Bulletin is attached for the Examiner's convenience.

used by itself for preparation of water gels.” This is consistent with the other references already submitted by the Applicants on this point. As a result, it would have been expected that such weakly gelling carrageenan would form weak gel films.

Moreover, Applicants respectfully submit that, rather than support the Examiner’s rejections, van de Velde actually supports the patentability of the present invention and stands for the proposition that, consistent with Applicants’ views regarding the knowledge in the field concerning kappa-2 carrageenan, kappa-2 carrageenan is different from iota carrageenan, kappa carrageenan and physical mixtures thereof and, because of such differences, one skilled in the art would not have known or expected kappa-2 carrageenan to be useful in the gel films, soft capsules and solid forms of the present invention.

That is, van de Velde is a technical article detailing a study that was aimed at determining whether the hybrids studied therein are mixed chains of kappa and iota repeating units or physical mixtures thereof. The reference states:

“The rheological properties of the gelling carrageenans (k and i) are quite distinct: the k-type forms gels that are hard, strong and brittle, whereas i-carrageenan forms soft and weak gels.”

See van de Velde at page 272, second column, lines 4-8 from the bottom.

“The gelation on cooling of k- or i-carrageenan solutions is generally accepted to proceed in two steps. The first step is the coil-to-helix transition from a disordered (random coil) to an ordered (helical) conformation...The gelation of the helical polymers (second step) can proceed on either a helical or superhelical level.”

See van de Velde at pages 278 and 279.

“The k/i-hybrid did not show a clear coil-to-helix transition...or any sudden change in the increase in viscosity with decreasing temperature....(emphasis added)....Chains that are composed of both k- and i- repeating units are expected to contain kinking sequences (k-units adjacent to i-units) that prevent a regular helix formation.”

See van de Velde at page 279, second column, first and second paragraphs (emphasis added).

As a result, van de Velde actually teaches that kappa-2 carrageenan would not be expected to be useful in the gel films, soft capsules and solid forms of the present invention. The teachings in van de Velde are consistent with the knowledge in the field that kappa-2 carrageenan was not known to be a gelling carrageenan such as kappa and iota. As a result, van de Velde supports Applicant's position that one skilled in the field would not have expected kappa-2 carrageenans to be useful in the films, soft capsules and solid forms of the present invention.

The Examiner has not provided any references demonstrating that kappa-2 carrageenan was known to be structurally similar to kappa carrageenan, iota carrageenan or physical mixtures between the two or any references demonstrating that kappa-2 carrageenan was known to have similar gelling properties as kappa carrageenan, iota carrageenan or physical mixtures between the two.

In view of the foregoing, Applicants respectfully submit that the presently claimed invention is unobvious and patentable over the cited prior art, alone or in any combination. Accordingly, withdrawal of the foregoing rejections is respectfully requested.

**35 USC § 103**

At pages 8-10 of the Office Action, the Examiner rejected claims 1, 12 and 31-33 under 35 USC § 103 as being unpatentable over Fonkwe in view of de Vries and van de Velde. The Examiner's position is that Fonkwe teaches a gel film, soft capsules and solid dosage forms comprising iota carrageenan, kappa carrageenan, plasticizer and bulking agent. The Examiner acknowledges that Fonkwe does not disclose the use of kappa-2 carrageenan, but relies on the teachings of de Vries and van de Velde as discussed in the foregoing

rejections to conclude that it would have been obvious to one skilled in the art to use kappa-2 carrageenan in a gel film composition.

Applicants respectfully traverse the foregoing rejection and request reconsideration thereof.

That is, as with Gilleland above, Fonkwe discloses the use of kappa and iota carrageenans, but, as also acknowledged by the Examiner, Fonkwe fails to disclose the use of kappa-2 carrageenan in a gel film application. Fonkwe discloses that there are “five distinct types of carrageenan” being “iota, kappa, lambda, mu and nu carrageenan” and that these “types of carrageenan can significantly vary in properties” (see Fonkwe at col. 1, lines 55-59).

For the reasons set forth above, neither de Vries nor van de Velde disclose and/or suggest that kappa-2 carrageenan can be used in the gel films, soft capsules and solid forms of the present invention. Van de Velde, as discussed above, actually teaches that kappa-2 carrageenan would not be expected to be useful in the gel films, soft capsules and solid forms of the present invention.

Accordingly, Applicants respectfully submit that the cited art, alone or in any combination, does not disclose or suggest the presently claimed invention. Withdrawal of the foregoing rejection is respectfully requested.

**35 USC § 103**

At pages 10-11 of the Office Action, the Examiner rejected claims 1 and 41 under 35 USC § 103 as being unpatentable over Augello in view of de Vries and van de Velde. The Examiner’s position is that Augello teaches a gel film composition comprising microcrystalline cellulose and carrageenan. The Examiner acknowledges that Augello does



not disclose the use of kappa-2 carrageenan, but again relies on the teachings of de Vries and van de Velde to conclude that it would have been obvious to one skilled in the art to use kappa-2 carrageenan in the gel film composition of the present invention.

Applicants respectfully traverse the foregoing rejection and request reconsideration thereof.

That is, Augello is directed to an edible coating composition comprising microcrystalline cellulose, carrageenan and either a strengthening polymer, plasticizer or both. Augello discloses the use of kappa carrageenan, iota carrageenan or lambda carrageenan. As the Examiner acknowledged, Augello fails to disclose the use of kappa-2 carrageenan therein. As a result, the Examiner again turns to de Vries and van de Velde.

For the reasons set forth above, none of de Vries or van de Velde disclose and/or suggest that kappa-2 carrageenan can be used in the gel films, soft capsules and solid forms of the present invention. Van de Velde, as noted above, actually teaches that kappa-2 carrageenan would not be expected to be useful in the gel films, soft capsules and solid forms of the present invention.

In view of the foregoing, it is respectfully submitted that the cited prior art, alone or in any combination, does not disclose or suggest the presently claimed invention. Accordingly, withdrawal of the foregoing rejection is respectfully requested.

**Obviousness-Type Double Patenting Rejection (Provisional)**

At pages 11-16 of the Office Action, the Examiner issued numerous provisional obviousness-type double patenting rejections. Applicants request that these rejections be held until such time as a notice of patentable subject matter has been received in the applications. An appropriate terminal disclaimer may be filed at that time, if necessary.

Applicants respectfully submit that the presently claimed invention is in condition for allowance. Early, favorable action is earnestly solicited.

Respectfully submitted,

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Attachment: Marine Colloids Application Bulletin, G-39, 1990

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